



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Food and Drug Administration/International Society for Pharmaceutical Engineering Co-Sponsorship Educational Workshop: Redefining the ‘C’ in CGMP (Current Good Manufacturing Practices): Creating, Implementing, and Sustaining a Culture of Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in co-sponsorship with the International Society of Pharmaceutical Engineering (ISPE), is announcing a conference entitled “Redefining the ‘C’ in CGMP: Creating, Implementing and Sustaining a Culture of Quality” Pharmaceutical Quality System (ICH Q10) Conference.

The conference will span 3 days and is dedicated to teaching the principles of CGMP, reaping the benefits that come from establishing and maintaining a state of control, implementing continual improvement, enhancing regulatory compliance, and meeting quality objectives every day. The conference will take place in Baltimore, MD, and will draw on the best industry and regulator contributors on this topic.

Date and Time: The conference will be held on June 11, 2013, from 8:30 a.m. to 5 p.m.; June 12, 2013, from 8 a.m. to 5 p.m.; and June 13, 2013, from 8 a.m. to 4:30 p.m.

Location: The event will be held at the Renaissance Baltimore Harborplace Hotel, 202 East Pratt St., Baltimore, MD 21201, 1-800-535-1201.

Contact Person: Nancy Berg, President, International Society for Pharmaceutical Engineering, 600 North Westshore Blvd., suite 900, Tampa, FL 33609, Web site: <http://www.ISPE.org/CGMP>.

Conference attendees are responsible for their own accommodations.

Registration: You are encouraged to register at your earliest convenience. The ISPE registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted to the conference will receive confirmation. Registration will close after available conference space is filled. Onsite registration will be available on a space available basis on the day of the public conference beginning at 7 a.m. on June 11, 2013. The cost of registration is as follows:

ISPE Member	\$1,545 (prior to May 13); \$1,745 (after May 13 and onsite)
ISPE Nonmember	\$1,905 (prior to May 13); \$2,115 (after May 13 and onsite)
ISPE New Member	\$1,814 (prior to May 13); \$2,014 (after May 13 and onsite)
Federal Government Employee registering prior to/after May 13	\$500
FDA Planning Committee Members and Invited Speakers	(free) Fee Waived
ISPE Active, Functional and Program Committee Members	\$1,005 (prior and after May 13)
Student (prior to/after May 13)	\$200
Individuals from Academia/Emerging Economy	\$1,005 (prior to May 13); \$1,135 (after May 13 and onsite)

Registration instructions: To register, please submit your name, affiliation, mailing address, phone number, fax number, and email address, along with a check or money order

payable to "ISPE." To register via the Internet, go to the ISPE Web site, www.ISPE.org, to confirm the prevailing registration fees.

Dated: May 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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